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Docket No. ORT-1548

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : SCHULTZ, T. et al.
Serial No. : 10/022,138
Filed : December 13, 2001
Title : Steroid Hormone Products and Methods for Preparing Them

Art Unit : 1616
Examiner : Qazi, S.

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to: Mail Stop Appeal Brief-Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on

September 27, 2005

(Date of Deposit)

Joseph S. Kentoffio

(Name of applicant, assignee, or Registered Representative)

/Joseph S. Kentoffio Reg. No. 33,189/

(Signature)

September 27, 2005

(Date of Signature)

ATTENTION: BOARD OF PATENT APPEALS AND INTERFERENCES

APPELLANTS' BRIEF PURSUANT TO 37 C.F.R. § 1.192

Dear Sir:

This is an appeal from the Final Rejection of March 15, 2005, a Notice of Appeal having been received by the USPTO on July 27, 2005. Appellants' Brief is being submitted on September 27, 2005.

The fees required under 37 C.F.R. § 1.17(f), and any required petition for extension of time for filing this brief and fees therefore, are addressed in the accompanying

TRANSMITTAL OF APPEAL BRIEF.

Pursuant to 37 C.F.R. § 1.192(a), this brief is transmitted in triplicate.

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REAL PARTY IN INTEREST

The real party in interest of the above-referenced patent application is Ortho-McNeil Pharmaceutical, Inc., having a principal place of business at Route 202, Raritan, NJ 08869.

RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences pending.

STATUS OF CLAIMS

Claims 1-8 stand rejected under 35 U.S.C. § 102(b) and, in the alternative, under § 103(b), in view of US Patent No. 5,858,405 (hereinafter "Gast").

STATUS OF AMENDMENTS

The claims stand amended as set forth in the Response To Office Action filed on December 15, 2004.

SUMMARY OF THE INVENTION

The present invention provides a steroid hormone product having an improved dissolution profile and release rate profile. The product comprises at least one steroid hormone in admixture with a primary excipient. Substantially all of the steroid hormone is in non-crystalline form, and it is stabilized in this form by the excipient. The hormone products taught by the invention are characterized by highly favorable dissolution properties. The preferred excipient for stabilizing the steroid in its non-crystalline form is lactose. The steroid hormone products of the invention are particularly useful as either oral contraceptives or HRT products. Specification at page 4, line 16 to page 6, line 3.

STATEMENT OF ISSUES

Whether claims 1-8 are anticipated by US Patent No. 5, 858,405, i.e., whether this references discloses each and every aspect of the claimed invention.

Whether claims 1-8 are obvious over US Patent No. 5, 858,405, i.e., whether a person skilled in the art would be lead by the teachings of the Gast reference to prepare the claimed invention.

GROUPING OF CLAIMS

For the purposes of this Appeal, all of the pending claims 1-8 stand or fall together.

ARGUMENTS

The Rejection Issued Under § 102(b)

Claims 1-8 have been rejected under 35 U.S.C. §§ 102(a) as being anticipated by Gast '405. Gast is not directed to steroid hormone formulations having improved dissolution and release rate properties. Rather, Gast provides a novel tri-phasic regimen for administering oral contraceptives, wherein a combination of an estrogen and a progestin are administered for 23-25 days followed by 3-5 days of estrogen-only administration. Gasts's formulations include a progestin and an estrogen and further include components such as colorants, lubricants, fillers and the excipient lactose. All of these components are well known in the art of formulating oral contraceptives. The novel aspects of Gast are directed to the dosages of the specified hormones and the particular ti-phasic contraceptive regimen taught by Gast.

Gast nowhere teaches a formulation wherein the steroid hormone in the formulation is in non-crystalline form and wherein the hormone is stabilized in this form by the excipient. Instead, and as specifically pointed out by Gast at column 9, line 67 to column 10, line 1, the formulations set forth in his Examples 1 and 2 are prepared by conventional methodology well known to those skilled in the art. The Examiner acknowledges in the Final Office Action that the instant claims differ from Gast in that the instant claims recite non-crystalline steroid hormone, and Gast teaches a crystalline form. Since Gast fails to teach each and every aspect of the claimed steroid hormone products, this reference cannot form the basis of a rejection under 35 U.S.C. § 102(b). MehlBiophile International Corp. v. Milgraum, 52 USPQ 2d 1303, 1306 (Fed. Cir. 1999). Accordingly, appellants request that the Board overturn this rejection.

The Rejection Issued Under § 103(a)

As to the 103(a) rejection, the Examiner argues that the claimed invention would be obvious since no unexpected results and/or criticality of the non-crystalline hormone is shown. Appellants submit the criticality of the steroid hormone in non-crystalline form is clearly set forth in the specification and that, accordingly, the rejection of the claims as obvious over Gast should be withdrawn.

Appellants direct the Board to page 6, lines 15-23, of the specification wherein it is noted that steroid hormones can exist in various solid state forms and that the particular solid state form may significantly affect properties such as dissolution rate and physical/chemical stability. It is further noted in this section of the specification that the higher energy, non-crystalline solid state form will exhibit an increase in dissolution rate over the more stable, lower energy crystalline form. At page 7, line 30 to page 8, line 2, appellants point out that

in the manufacture of steroid hormone products it would be highly desirable to increase the dissolution rate of the hormone while at the same time either improving or at least not reducing the physical/chemical stability of the hormone.

These objectives are achieved by the claimed invention, as shown by the data set forth in Tables 1-4. In particular, the data in Table 1 demonstrate the difference in dissolution rates for non-crystalline norgestimate as compared to the lower-energy crystalline form. Note that the dissolution rate for amorphous norgestimate at 60 minutes is about the same as the lower energy crystalline form at 120 minutes and that the dissolution rate for the amorphous form at 120 minutes is significantly higher than the rate for the crystalline form at 140 minutes. The data in Tables 2 and 3 illustrates the effect on dissolution rate as norgestimate begins to re-crystallize from the higher energy amorphous form. As shown by these data, the dissolution rate of norgestimate decreases as the steroid converts to the lower energy crystalline form. The data in Table 4 show that the dissolution properties of norgestimate are not only dependent on storage conditions, but also on the mixing energetics imparted during the manufacturing process. Note that as energy is imparted over time and higher levels of amorphous norgestimate are present, the dissolution characteristics improve even when storage is unprotected under accelerated conditions.

As stated in the specification at page 13, lines 11-22, taken together the data from these studies demonstrate that when a mixture of an excipient and a steroid active ingredient is subjected to sufficient mechanical energy, the excipient and the steroid active ingredient form a less crystalline, more highly energetic composition. Furthermore, under appropriate mixing conditions, the lactose component stabilizes the steroid in a highly energetic, substantially non-crystalline state, thus preventing recrystallization of the steroid. The highly energetic, non-crystalline steroid active

ingredient dissolves more readily and is better able to maintain desirable dissolution characteristics under a variety of conditions of ambient humidity and ambient temperature.

The portions of the specification cited above establish the criticality of the non-crystalline steroid hormone and the unexpected results that derive from this form of hormone. Where, as here, the specification contains specific data indicating substantially improved properties, unexpected results are established, absent evidence to the contrary.

In re Soni, 34 USPQ 2d 1684, 1687-88 (Fed. Cir. 1995).

In view of the foregoing, appellants request that the Examiner's Final Rejection be overturned and that this application be passed to allowance at the earliest possible date.

Please charge the fee of \$330.00 required under 37 C.F.R § 1.17(c), any deficiency in this fee and any other fees that may be required in connection with the filing of appellants' Appeal Brief to Deposit Account No. 10-0750/ORT-1548/JSK.

Appellants' Appeal Brief is being filed in triplicate.

Respectfully submitted,

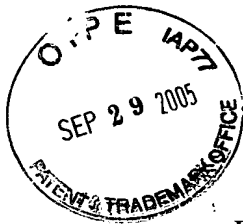
By: /Joseph S. Kentoffio/

Joseph S. Kentoffio
Reg. No. 33,189

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(732) 524-3711
Dated: September 27, 2005

APPENDIX OF CLAIMS

1. A steroid hormone product having improved dissolution and release rate properties, said product comprising at least one steroid hormone in admixture with an excipient, wherein substantially all of said at least one steroid hormone is in non-crystalline form and wherein said excipient stabilizes said hormone in its non-crystalline form.
2. The steroid hormone product of claim 1, wherein the primary excipient is selected from the group consisting of dextrose, fructose, sorbitol, xylitol, sucrose, lactose, mannitol, dextrate, cellulose, starch and mixtures thereof.
3. The steroid hormone product of claim 1 wherein the steroid hormone is at least one of a progestin and an estrogen
4. The steroid hormone product of claim 3, wherein the steroid hormone is a progestin selected from the group consisting of norgestimate, norgestrel, levonorgestrel, norethindrone and desogestrel.
5. The steroid hormone product of claim 4 wherein the steroid hormone is norgestimate and the excipient is lactose.
6. The steroid hormone product of claim 3, wherein the product is one of an oral contraceptive product and a hormone replacement therapy product.
7. The steroid hormone product of claim 6, wherein the product is an oral contraceptive product comprising from about 10 μg to about 50 μg of an estrogen and/or from about 50 μg to about 300 μg of a progestin.
8. The steroid hormone product of claim 7, wherein the progestin is norgestimate and the excipient is lactose.



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Commissioner For Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPEAL BRIEF TRANSMITTAL

Dear Sir:

Enclosed is an Appeal Brief for the above-referenced patent application.

Please charge Deposit Account No. 10-0750/ORT-1548/JSK in the name of Johnson
& Johnson for the cost of filing this Appeal Brief. Three copies of this Transmittal are
enclosed.

Respectfully submitted,

/Joseph S. Kentoffio/
Joseph S. Kentoffio
Reg. No. 33,189
Attorney for Applicants

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(732) 524-3711
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